DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Medical Imaging Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Medical Imaging Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 28 and 29, 1999, 8 a.m. to 5 p.m.

Location: Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Leander B. Madoo, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12540. Please call the Information Line for up-to-date information on this meeting.

Agenda: Section 121 of FDA's Modernization Act of 1997 directs FDA to establish appropriate procedures for the approval of positron emission tomography (PET) drugs under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 355). At this meeting, FDA will present its findings on the safety and effectiveness of three PET drugs: (1) Fludeoxyglucose F 18 Injection, (2)Ammonia N 13 Injection, and (3) Water 0 15 Injection, for particular indications based on review of published literature. The committee will discuss the safety and effectiveness data on these three drugs. FDA also will discuss its proposed procedures for obtaining marketing approval for these three PET drugs.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by June 18, 1999. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9:30 a.m., June 28, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 18, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 28, 1999

Jane E. Henney
Commissioner of Food and Drugs

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